

Translation

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PATENT COOPERATION TREATY

PCT/JP2003/014251



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

10/5 33 659

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KW0132	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/014251	International filing date (day/month/year) 10 November 2003 (10.11.2003)	Priority date (day/month/year) 11 November 2002 (11.11.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/7004, 31/7016, 33/18, 47/02, 47/44, A61P 17/00		
Applicant KOWA CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report   |
| <input type="checkbox"/> Box No. II           | Priority  |
| <input type="checkbox"/> Box No. III          | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV           | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI           | Certain documents cited   |
| <input type="checkbox"/> Box No. VII          | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII         | Certain observations on the international application   |

Date of submission of the demand 14 April 2004 (14.04.2004)	Date of completion of this report 14 October 2004 (14.10.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-4	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-4	NO
Industrial applicability (IA)	Claims	1-4	YES
	Claims		NO

### 2. Citations and explanations

- Document 1: JP 2002-226381 A ((Mikasa Seiyaku Co., Ltd.),  
14 August 2002
- Document 2: JP 2001-122790 A ((Mikasa Seiyaku Co., Ltd.),  
8 May 2001
- Document 3: JP 7-145081 A (Euroceltique S.A.), 6 June  
1995
- Document 4: JP 2002-516265 A (Euroceltique S.A.), 4 June  
2002
- Document 5: JP 2002-516266 A (Euroceltique S.A.), 4 June  
2002
- Document 6: JP 10-114710 A (Mitsubishi Chemical Ind.,  
Ltd.), 6 May 1998

(i) The inventions set forth in claims 1-4 do not involve an inventive step in the light of documents 1 and 2, cited in the international search report.

Document 1 discloses preparations containing a sugar and popidone iodine for treating wounds (claims and paragraph [0009]). It also mentions additives including pH adjusters and emulsifiers such as hydrogenated lecithin, and indicates that the moisture content is 1 w/w% or less (paragraphs [0013] and [0014]).

Document 2 discloses preparations containing a sugar, popidone iodine, white sugar and pure water for

treating wounds (claim 1, paragraph [0008] and examples 3-5), mentions emulsifiers such as hydrogenated lecithin as additives (paragraph [0010]), and indicates that the pH of the preparation is 4-6 (paragraph [0006]).

Therefore, inclusion of an emulsifier such as hydrogenated lecithin in an invention disclosed in documents 1 and 2 is a suitable option available to a person skilled in the art; and there appears not to be any special effect due to said feature.

(ii) The inventions set forth in claims 1-4 do not involve an inventive step in the light of documents 3, 4 and 5, cited in the international search report.

Document 3 discloses preparations in the form of a medicinal ointment containing a liposome preparation, as medicinal preparations of antiseptics and promoters of wound healing for external use (claims 1 and 15). It also mentions that the antiseptic is popidone iodine (claim 4) and mentions liposome-forming systems such as hydrogenated soybean lecithin (paragraph [0007]). Moreover, it also indicates that said liposomes can be redispersed in an electrolyte solution which includes a sugar (paragraph [0012]).

Document 4 discloses agents for promoting wound healing which are in the form of a medicinal ointment containing liposomes as a carrier, with popidone iodine as an antiseptic (claims 1-17). Hydrogenated soybean lecithin is also mentioned as an amphiphilic substance which forms liposomes (paragraph [0013]). Moreover, it is also mentioned that said liposomes can be redispersed in an electrolyte solution which includes a sugar (paragraph [0023]).

Document 5 discloses agents for promoting wound healing which contain liposomes as a carrier, with popidone iodine as an antiseptic (claims 1-6).

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Hydrogenated soybean lecithin is also mentioned as an amphiphilic substance which forms liposomes (paragraph [0013]). Moreover, it also indicates that said liposomes can be redispersed in an electrolyte solution which includes a sugar (paragraph [0023]).

Therefore, a person skilled in the art could easily conceive of including a sugar in the inventions disclosed in documents 3-5 and optimising the pH by suitable modification; and there appears not to be any special effect due to said feature.

(iii) The inventions set forth in claims 1-4 do not involve an inventive step in the light of documents 1, 2 and 6.

Document 6 indicates that by adding an anionic surfactant such as a lecithin compound to a highly viscous aqueous solution of a sucrose fatty acid, the viscosity of the aqueous solution is lowered, and storage properties and ease of processing are considerably improved (paragraphs [0003], [0005] and [0006]).

Therefore, a person skilled in the art could easily conceive of adding a lecithin compound in order to decrease the viscosity of the aqueous solution in the inventions disclosed in documents 1-2; and there appears not to be any special effect due to said feature.